



UNITED STATES PATENT AND TRADEMARK OFFICE

CK

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,553	08/14/2003	Wouter Cornelis Puijk	2183-6064US	3138
24247	7590	05/27/2005	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			LUM, LEON YUN BON	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,553

Applicant(s)

PUIJK ET AL.

Examiner

Leon Y. Lum

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RD

DETAILED ACTION

1. The amendment filed 28 March 2005 is acknowledged and has been entered.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-6 in the reply filed on 28 March 2005 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Uo et al (US 4,803,154).

In the instant claims Uo et al reference teaches a spot-membrane (i.e. micro-array support), wherein the membrane is a hydrophobic polymer sheet with a number of hydrophilic spots (i.e. support surface with surface patches interspersed within surface areas; surface patches and surface areas are materially distinct). See column 3, lines 39-41; column 4, lines 34-37; and Figure 1.

Art Unit: 1641

With regards to claim 3, Uo et al teach that the spot-membrane comprises a hydrophobic polypropylene polymer sheet and that spots on the hydrophobic sheet comprise glutaraldehyde, wherein the glutaraldehyde is hydrophilic, as is well known to one of ordinary skill in the art, and provides the hydrophilic spots on the spot-membrane. See column 4, lines 6-23.

With regards to claim 6, Uo et al teach that that spots are formed in 4 to 32 spots per each membrane in a size of 0.5 to 15 mm in diameter (at least 25 patches per square centimeter). See column 4, lines 41-44.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uo et al (US 4,803,154) in view of Drumheller (US 5,874,165).

Uo et al reference has been disclosed above, and additionally teaches that the spots have antibody immobilized thereon. See column 4, lines 24-34. However, Uo et al fail to teach that the hydrophilic material comprises polyacrylic acid.

Drumheller reference teaches a support member comprising a hydrophobic polymeric support of polypropylene and 1st and 2nd layers of hydrophilic polyacrylic acid, in order to provide layers of chemically stable hydrophilic polymers to stably immobilize bioactive species. See column 10, lines 47-51; column 11, lines 14-19 and 61-66; column 12, lines 1-2; and column 14, lines 51-54. Drumheller also teaches that the bioactive species can include antibodies. See column 16, line 26.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Uo et al, with a support member comprising a

Art Unit: 1641

hydrophobic polymeric support of polypropylene and 1st and 2nd layers of hydrophilic polyacrylic acid, as taught by Drumheller, in order to provide layers of chemically stable hydrophilic polymers to stably immobilize bioactive species. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including hydrophilic polyacrylic acid, as taught by Drumheller, in the apparatus of Uo et al, since Uo et al teach substrate surfaces that include hydrophilic areas with immobilized antibodies, and the polyacrylic acid layer taught by Drumheller is one type of hydrophilic material that can also immobilize antibodies.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uo et al (US 4,803,154) in view of Rowe et al (Analytical Chemistry, 1999, 71).

Uo et al reference has been disclosed above and additionally an immuno-active substance is immobilized on the spot-membrane, wherein the substance is an antibody and is in a plurality of spot locations (i.e. tentative first member binding molecules arranged in spatially addressable spots). See column 4, lines 24-33 and Figure 1. However, Uo et al reference fails to disclose a library of tentative first member binding molecules.

Rowe et al reference teaches a plurality of unique antibodies on a biosensor surface, in order to simultaneously measure multiple diverse analytes on a single substrate. See Table 1; Figure 1 and caption; and page 3851, right column, 3rd paragraph, lines 1-4.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Uo et al, with a plurality of unique antibodies on a biosensor surface, as taught by Rowe et al, in order to simultaneously measure multiple diverse analytes on a single substrate. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in providing different types of antibodies, as taught by Rowe et al, in the apparatus of Uo et al, since both Rowe et al and Uo et al references teach a plurality of antibody spot locations on a single substrate surface.

Response to Arguments

10. Applicant's arguments, see page 10 of the Remarks, filed 28 March 2005, with respect to the terms "materially" and "library" have been fully considered and are persuasive. The 35 U.S.C. 112, second paragraph rejections of claims 1 and 5 with respect to the terms "materially" and "library", respectively, have been withdrawn.

11. Applicant's arguments with regards to the rejections under 35 U.S.C. 103(a), filed 28 March 2005 have been fully considered but they are not persuasive.

On pages 10-11, Applicants argue that Uo et al do not teach a spot density of at least 25 spots per square centimeter and point to cited passage in column 4, lines 37-39, which state that the membrane is 2 to 12 by 6 to 20 centimeters. Applicants then calculate an area of 12 square centimeters by taking the smallest of the two dimensions

Art Unit: 1641

and, applying the 12 square centimeters as the denominator in a fraction with the disclosed 32 spots, arrives at 2.67 spots per square centimeter and state that Uo et al therefore do not teach the claimed limitation (see page 11, 2nd paragraph). In addition, Applicants contend that since Drumheller and Rowe et al do not teach the claimed limitation, they do not render the claims obvious.

However, the cited text in Uo et al, as stated in the previous Office Action and restated in the rejection *supra*, is not directed at the dimensions that Applicants used in the arguments. Uo et al teach membranes that are 0.5 to 15 mm in diameter, with 4 to 32 spots per membrane. See column 4, lines 41-44. Since the membrane dimension is in terms of diameter, the membrane is circular and the area of a circle is πr^2 . Converting the smallest dimension into centimeters (0.5 mm = 0.05 cm) and applying the equation for the area of a circle, the membrane dimension is 0.0079 cm². Taking the largest number of spots per membrane disclosed, 32 spots, and dividing this number by the calculated membrane dimension produces 4050 spots per square centimeter, which clearly teaches the claimed limitation of at least 25 patches per square centimeter. Therefore, since Uo et al teach the claimed limitation, Drumheller and Rowe et al are not relied upon to teach the instant limitation, and Applicants' arguments are therefore not found persuasive. The rejection made in the previous Office Action is maintained.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641



LYL



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/25/05